35 U.S.C. §112

In the prior Office Action, claims 3-7, 13-17, 24, 26-36, 38, 40-41, 46-47 and 53-57 were rejected under 35 U.S.C. §112, first paragraph, on grounds that the specification did not reasonably provide enablement for the treatment of chronic disorders of the central nervous system with Colostrinin. By this Amendment, claims 3-7, 13, 14, 17, 33, 34, 36, 46, 47, 53 and 55-57 have been canceled, thus rendering the prior rejection thereof moot. All of the remaining claims have been amended. Applicants respectfully submit that amended claims 15, 16, 24, 26-32, 35, 40, 41 and 54 now clearly meet the requirements of 35 U.S.C. §112, first paragraph.

Claim 15 claims a medicament comprising a therapeutic unit of Colostrinin in isolated form for use in the treatment of dementia and/or neurodegenerative diseases in humans. Claim 16 claims a medicament comprising a therapeutic unit of Colostrinin in isolated form for use in the treatment of Alzheimer's disease in humans. Alzheimer's disease is a specific neurodegenerative disease. Claims 24 and 26-30 claim a method of treating a human patient afflicted with dementia and/or a neurodegenerative disease, the method comprising administering a therapeutic unit (defined in claim 27 as comprising from about 25 to 1000 micrograms) of Colostrinin in isolated form to the human patient about one or two times per day for a predetermined period of time. And, claims 31, 32 and 35 claim a pharmaceutical composition for oral administration to a human patient in the treatment of dementia and/or a neurodegenerative disorder, the pharmaceutical composition comprising a therapeutic unit of Colostrinin in isolated form

in combination with a physiologically acceptable carrier. The specification clearly teaches that administration of a therapeutic unit of Colostrinin in isolated form provides benefits in the treatment of dementia and/or neurodegenerative diseases, including Alzheimer's disease (see, in particular, Examples XII through X).

Claims 40 and 41 claim a dietary supplement for humans comprising a therapeutic unit of Colostrinin in isolated form. And, claim 54 claims a pharmaceutical composition for oral administration to a human patient comprising a nonapeptide having the amino acid sequence Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro (SEQ ID NO:1) in isolated form in combination with a physiologically acceptable carrier. The specification is clearly enabling for such claims (see, e.g., page 3, line 23 to page 4, line 4; and page 10, lines 5-15). In view of the foregoing, reconsideration of the rejection of claims 15, 16, 24, 26-32, 35, 40, 41 and 54 under 35 U.S.C. §112, first paragraph, is respectfully requested.

35 U.S.C. §103

In the prior Office Action, the Examiner maintained the rejection of claims 3-7, 13-17, 24, 26-36, 38, 40-41, 46-47 and 53-57 under 35 U.S.C. §103(a) as being unpatentable over Janusz et al., "Proline-Rich Polypeptide (PRP) - an Immunomodulatory Peptide from Ovine Colostrum", Archivum Immunologiae et Therapiae Experimentalis, 1993, pages 175-279 (hereinafter "the cited Janusz et al. reference"), as set forth in the Office Action mailed November 23, 2001 (Paper No. 19).

By this amendment, claims 3-7, 13, 14, 17, 27, 33, 34, 36, 46, 47, 53 and 55-57 have been canceled, thus rendering the rejection thereof moot. All of the remaining claims have been amended. Applicants respectfully submit that amended claims 15, 16, 24, 26, 28-32, 35, 40, 41 and 54 are patentable over the cited Janusz et al. reference.

The cited Janusz et al. reference discusses various studies of Colostrinin on mice and suggests that Colostrinin may be therapeutic in treating autoimmune disorders in mice. The cited Janusz et al. reference also states that Colostrinin may also be useful as a tool in studying the mechanisms of the immune system. However, the cited Janusz et al. reference clearly does not teach, suggest, or disclose the use of Colostrinin in humans, and in particular does not suggest that specified amounts of Colostrinin in isolated form may be useful for treating dementia and/or neurodegenerative diseases in humans or as a dietary supplement in humans.

All of the claims pending in the application relate to the use of Colostrinin in treating dementia and/or neurodegenerative diseases in humans or as a dietary supplement. The cited Janusz et al. reference clearly does not suggest the desirability of the claimed invention, as there is no suggestion or motivation in such reference to use a therapeutic unit of Colostrinin in isolated form to treat dementia and/or neurodegenerative diseases in humans. Applicants contend that there is no reasonable expectation of success that if a material is identified as having immunological activity in mice, it will also have a beneficial use in the treatment of dementia and/or neurodegenerative diseases in humans and/or be useful as a dietary supplement in

humans. The literature is replete with compounds that have some activity in mice, but none in humans, and vice versa. Applicants respectfully submit that the pending claims are clearly not obvious in view of the cited reference under 35 U.S.C. §103.

CONCLUSION

In light of the foregoing, it is submitted that claims 15, 16, 24, 26, 28-32, 35, 40, 41 and 54 are in condition for allowance, and a notice to that effect is therefore earnestly solicited.

Respectfully submitted,

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ATTACHMENT A

(Version of Claims With Markings Showing Changes Made)

15. (TWICE AMENDED) [~~The~~] A medicament [~~according to claim 14~~] comprising a therapeutic unit of Colostrinin in isolated form for use in the treatment of dementia and/or neurodegenerative diseases in humans.

16. (TWICE AMENDED) [~~The~~] A medicament [~~according to claim 14~~] comprising a therapeutic unit of Colostrinin in isolated form for use in the treatment of Alzheimer's disease [~~and/or motor neurone disease~~] in humans.

24. (THRICE AMENDED) A method of treating [~~disorders of the central nervous system~~] a human patient afflicted with dementia and/or a neurodegenerative disease, the method comprising administering a [~~predetermined amount of a~~] composition comprising a therapeutic unit of Colostrinin in isolated form to [a] the human patient about one or two times per day for a predetermined period of time.

26. (THRICE AMENDED) [A] The method according to claim 24 wherein the Colostrinin is non-ovine Colostrinin.

27. (TWICE AMENDED) A method according to claim 26, wherein said [~~predetermined amount~~] therapeutic unit of Colostrinin is in the range of about 25 to [~~2000~~] 1000 micrograms.

28. (AMENDED) [~~A~~] The method according to claim 27 [~~, comprising a cycle of administering 25 to 2000 micrograms~~] wherein the therapeutic unit of Colostrinin in isolated form is administered to the patient about one or two times each day [~~to a patient~~] for a first period of time, followed by a second period of time when no Colostrinin is administered.

29. (AMENDED) [~~A~~] The method according to claim 28[~~,~~] wherein the first period of time is in the range of about 2 to 4 weeks, and the second period of time is in the range of about 2 to 5 weeks.

30. (TWICE AMENDED) [~~A~~] The method according to claim 28[~~,~~] wherein [the] a cycle of administering Colostrinin in isolated form for a first period of time followed by a second period of time when Colostrinin is administered is repeated at least once.

31. (THRICE AMENDED) A pharmaceutical composition for oral administration to a human patient in the treatment of dementia and/or a

neurodegenerative disorder, the pharmaceutical composition comprising a [~~preselected amount~~] therapeutic unit of Colostrinin in isolated form in combination with a physiologically acceptable carrier.

32. (AMENDED) [~~A~~] The pharmaceutical composition according to claim 31[~~,~~] wherein the Colostrinin is non-ovine Colostrinin.

35. (FOUR TIMES AMENDED) [~~A~~] The pharmaceutical composition according to claim 31 in the form of a tablet, lozenge or gel.

40. (TWICE AMENDED) A dietary supplement for [~~babies, small children, adults who have been subjected to chemotherapy and/or adults who have suffered from cahexia, or weight loss due to chronic disease,~~] humans comprising a therapeutic unit of Colostrinin in isolated form.

41. (TWICE AMENDED) A dietary supplement for humans comprising an orally ingestible combination of a therapeutic unit of Colostrinin in an isolated form in combination with a physiologically acceptable carrier.

54. (THRICE AMENDED) A pharmaceutical composition for oral administration to a human patient comprising a nonapeptide having the amino acid

sequence Val-Glu-Ser-Tyr-Val-Pro-Leu-Phe-Pro (SEQ ID NO:1) in isolated form in combination with a physiologically acceptable carrier.